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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,539

02/03/2005

Kenji Sunagawa

KUP-5

7546

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,539	<b>Applicant(s)</b> SUNAGAWA ET AL.	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080811</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graupe (US 5,016,635, hereinafter "Graupe").

4. In regards to claim 7, Graupe discloses the essential features of the claimed invention including a biological activity sensing means (60); a calculating means (50) that receives biosignals, calculates a plurality of signals for stimulation of an organism using an impulse response transfer function previously obtained from normal biological activities wherein the transfer function is an inverse Fourier transform of a transfer function which is based on a Fourier transfer of the biosignals (col. 4, lines 12-20); and

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an organism stimulating means responsive to the signals (40). Graupe does not explicitly disclose that the stimulation signals are calculated using a convolution integral between the impulse response and the biosignals. It is well known in the signal analysis arts to apply transfer functions to input signals by convolution integral to determine output signals to provide the predictable result of determining output parameters in the time domain without requiring transform to the frequency domain. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Graupe's invention by applying the transfer function to input signals by convolution integral to determine the output signals to provide the predictable result of determining output parameters in the time domain without requiring transform to the frequency domain.

5. In regards to claims 8 and 10, the sensing means is electrodes and the stimulation means is electrical (col. 2, line 61).

6. In regards to claim 12, the calculating means comprises a discriminating means which determines whether the biosignals are caused by normal or abnormal (fatigue-indicating) activities, and outputs/does not output the signals for stimulation accordingly (col. 4, lines 3-20).

7. In regards to claims 9 and 11, Graupe discloses the claimed invention except for utilizing biosignals selected from the claimed group, or that the calculating means comprises an amplifier, A-D converter, and an analyzer. It is well known in the electrical stimulation arts to utilize closed-loop control similar to that disclosed by Graupe using sympathetic/parasympathetic nerve activity, blood flow, blood temperature, ECG, EEG,

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or various biochemical markers to provide the predictable result of maintaining stimulation parameters within physiologically beneficial limits, and to provide processors/calculating means with amplifiers, A-D converters, and analyzers to provide the predictable result of allowing signal modification and analysis to be performed with the inexpensive and ubiquitous digital microprocessor. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Graupe's invention by utilizing sympathetic/parasympathetic nerve activity, blood flow, blood temperature, ECG, EEG, or various biochemical markers to provide the predictable result of maintaining stimulation parameters within physiologically beneficial limits in other stimulation settings; and to provide a calculating means with an amplifier, A-D converter, and analyzer to provide the predictable result of allowing signal modification and analysis to be performed with the inexpensive and ubiquitous digital microprocessor.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 7-12 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Oung et al. (US 7,079,888) is one of many teachings of determining an output signal via convolution integral between input and transfer functions and utilizing autonomic nervous system activity as the sensed biosignal, and

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Burton (US 5,423,325) is one of many teachings of utilizing an amplifier, A-D converter, and analyzer in a biosignal analysis unit.

**10.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHAEL KAHELIN** whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Michael Kahelin/  
Examiner, Art Unit 3762